PATENT COOPERATION TREATY

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From the INTERNATIONAL SEARCHING AL	JTHORITY	PACT 2003 CASEA / LH
To: JOHNSON & JOHNSON Attn. Johnson, Philip, S. One Johnson & Johnson Plaza New Brunswick, NJ 08903 UNITED STATES OF AMERICA	Searci US Ref	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT RESPONSE—FOR THE DECLARATION 5-6-0-3 (PCT Rule 44.1) 6-6-0-3
		Date of malling (day/month/year) 06/03/2003
Applicant's or agent's file reference MCP-242	•	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US 02/30614		International filing date (day/month/year) 26/09/2002
Applicant		
MCNEIL-PPC, INC.	·	

		_
1.	The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.	
	Filing of amendments and statement under Article 19:	
	The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):	
	When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.	
	Where? Directly to the International Bureau of WIPO	
	34, chemin des Colombettes	
	1211 Geneva 20, Switzerland	
•	Fascimile No.: (41–22) 740.14.35	
	For more detailed instructions, see the notes on the accompanying sheet.	
2. [The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.	
з. [With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:	
	the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.	
	no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.	
4. F	urther action(s): The applicant is reminded of the following:	•
	hortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, befor the completion of the technical preparations for international publication.	
	fithin 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (In some Offices even later).	
•	rithin 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later lection within 19 months from the priority date or could not be elected because they are not bound by Chapter II.	

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (c ntinued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new:
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
 "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]:
 "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
 "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
 "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

it must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MCP-242	FOR FURTHER see Notification (Form PCT/ISA	(Form PCT/ISA/200) as well as where applicable the second				
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)				
PCT/US 02/30614	26/09/2002	28/09/2001				
Applicant						
MCNEIL-PPC, INC.						
This International Search Report has been according to Article 18. A copy is being train	prepared by this International Searching Aunsmitted to the International Bureau.	thority and is transmitted to the applicant				
This International Search Report consists of X It is also accompanied by a	of a total of sheets. a copy of each prior art document cited in this	s report.				
1. Basis of the report						
 With regard to the language, the in language in which it was filed, unles 	nternational search was carried out on the ba ss otherwise indicated under this item.	sis of the international application in the				
the international search was Authority (Rule 23.1(b)).	s carried out on the basis of a translation of t	he international application furnished to this				
The basis of the s	sequence isling :	nternational application, the international search				
	al application in written form.					
	ational application in computer readable form	n				
furnished subsequently to th						
	is Authority in computer readble form.					
the statement that the subse international application as fi	equently furnished written sequence listing do illed has been furnished.	pes not go beyond the disclosure in the				
the statement that the inform furnished	nation recorded in computer readable form is	identical to the written sequence listing has been				
2. Certain claims were found	unsearchable (See Roy I)					
3. Unity of invention is lacking	· · · · · · · · · · · · · · · · · · ·					
4. With regard to the title,						
X the text is approved as submi	itted by the applicant.					
·	by this Authority to read as follows:					
	*					
. With regard to the abstract,	•					
the text is approved as submit	ted by the applicant.	·				
the text has been established.	according to Rule 38.2(b), by this Authority e of mailing of this international search repor	as it appears in Box III. The applicant may, t, submit comments to this Authority				
The figure of the drawings to be published		29				
as suggested by the applicant.						
H		None of the figures. NONE OF THE FIGURE AVAILABLE COPY				

International application No.

PCT/US 02/30614

INTERNATIONAL SEARCH REPORT

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Systems, methods and apparatuses for manufacturing dosage forms, and to dosage forms made using such systems, methods and apparatuses are provided. Novel compression, thermal cycle molding, and thermal setting molding modules (200) are disclosed. One or more of such modules may be linked, preferably via novel transfer device, into an overall system for making dosage forms.

INTERNATIONAL SEARCH REPORT

International Application No PCT/IIS 02/30614

•	•	!	rc1/05 02	/30614
A. CLASS IPC 7	B30B11/34 A61J3/10			
<u>_</u>	to International Patent Classification (IPC) or to both national class S SEARCHED	ssification and IPC		
	ocumentation searched (classification system followed by classification sy	fication symbols)		
IPC 7	B30B A61J A61K			
Documenta	ation searched other than minimum documentation to the extent t	hat such documents are include	ed in the fields se	earched
Electronic	data base consulted during the international search (name of dat	a base and, where practical, so	earch terms used	<u> </u>
EPO-In	ternal	•		
				•
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	· ·		·
Category °	Citation of document, with indication, where appropriate, of the	e relevant passages		Relevant to claim No.
Α .	GB 759 081 A (FRANK THOMAS STOT HOLROYD AND COMPANY LTD) 10 October 1956 (1956-10-10)	T; JOHN		1,16,20, 24,34
X	the whole document			28-31,44
X	WO 01 15889 A (VOSS GUNTER M) 8 March 2001 (2001-03-08) the whole document			28-31
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Furthe	r documents are listed in the continuation of box C.	χ Patent family mem	bers are listed in	annex.
Special cate	gories of cited documents:	"T" later document published	d often the linter-	Alamat Allian data
consider	defining the general state of the art which is not ed to be of particular relevance	or priority date and not cited to understand the invention	in conflict with the	application but
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which is citation o	which may throw doubts on priority claim(s) or cited to establish the publication date of another r other special reason (as specified)	involve an inventive ster "Y" document of particular re cannot be considered to	p when the docum elevance; the clain	nent is taken alone ned invention
other me document	referring to an oral disclosure, use, exhibition or ans published prior to the international filling date but the priority date claimed	document is combined to ments, such combination in the art.	with one or more on the control of t	other such docu- o a person skilled
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/30614

Patent docum nt cited in search report		Publication date		Patent family member(s)	Publication date
GB 759081	Α	10-10-1956	NONE		
WO 0115889	A .	08-03-2001	DE AU WO DE EP	19941997 A1 1267201 A 0115889 A1 10082551 D2 1212191 A1	08-03-2001 26-03-2001 08-03-2001 03-01-2002 12-06-2002